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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,356	09/02/1999	DARIO NERI	515-4132	3100
23599	7590	11/21/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	
DATE MAILED: 11/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/194,356	Applicant(s) NERI ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-47, 53-55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-37, 43-45, 47, 53-55 and 57-61 is/are rejected.
- 7) ☒ Claim(s) 38-42 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/09/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Claims 30-47, 53-55 and 58-61 are pending.
Claims 30-47, 53-55 and 58-61 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Compliance

3. The disclosure is no longer objected to because Applicants kindly pointed out to the Examiner that amendments were made to the specification including identifying SEQ ID Numbers on December 28, 2000.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The rejection of claims 30-37, 43, 55, 57, 59 and 60 under 35 U.S.C. 102(b) as being anticipated by JP(A) H2-76598 (laid open March 15, 1990)/ IDS reference number 23, submitted February 8, 2005 is maintained.

Applicants have submitted a letter establishing the deposited antibodies reported in the Japanese patent do not bind the ED-B domain of fibronectin signed by said patent inventor, Kiyotoshi Sekiguchi, Ph.D., which accompanied the Remarks submitted August 31, 2005. Applicants also aver that this document does not support an

anticipation rejection because the document is purportedly not enabling for production of an antibody binding to the ED-B domain of FN. This letter and Applicants' points of view have been carefully considered, but found unpersuasive.

Applicants have submitted a letter, which is not a declaration or an affidavit and clearly does not contain the clause regarding "willful false statements..." required by 37 CFR 1.68 has been omitted. Moreover, the Japanese patent reference is a statutory bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131. Accordingly, the rejection is maintained.

5. The rejection of claims 30-37, 43, 47, 55, 57 and 59-61 under 35 U.S.C. 102(b) as being anticipated by JP(A) H4-169195 (laid open June 17, 1992)/ IDS reference number 24, submitted February 8, 2005 is maintained.

Applicants have submitted a letter establishing the deposited antibodies reported in the Japanese patent do not bind the ED-B domain of fibronectin signed by said patent inventor, Kiyotoshi Sekiguchi, Ph.D., which accompanied the Remarks submitted August 31, 2005. Applicants also aver that this document does not support an anticipation rejection because the document is purportedly not enabling for production of an antibody binding to the ED-B domain of FN. This letter and Applicants' points of view have been carefully considered, but found unpersuasive.

Applicants have submitted a letter, which is not a declaration or an affidavit and clearly does not contain the clause regarding "willful false statements..." required by 37 CFR 1.68 has been omitted. Moreover, the Japanese patent reference is a statutory

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bar under 35 U.S.C. 102(b) and thus cannot be overcome by an affidavit or declaration under 37 CFR 1.131. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

6. The rejection of claims 30-37, 43-45, 55, 57-59 and 60 under 35 U.S.C. 103(a) as being unpatentable over JP(A) H2-76598 (laid open March 15, 1990)/ IDS reference number 23, submitted February 8, 2005, in view of Bird et al. (Science 242:423-242, 1988) is maintained.

For the reasons of record listed above in paragraphs 4 and 5 the 102(b) rejection is maintained and accordingly the instant 103(a) rejection is maintained.

7. The rejection of claims 30-37, 43-45, 47, 55 and 57-61 under 35 U.S.C. 103(a) as being unpatentable over JP(A) H4-169195 (laid open June 17, 1992)/ IDS reference number 24, submitted February 8, 2005, in view of Bird et al. (Science 242:423-242, 1988) is maintained.

For the reasons of record listed above in paragraphs 4 and 5 the 102(b) rejection is maintained and accordingly the instant 103(a) rejection is maintained.

8. The rejection of claims 30-37, 43, 47 and 53-57 under 35 U.S.C. 103(a) as being unpatentable over JP(A) H2-76598 (laid open March 15, 1990)/ IDS reference number 23, submitted February 8, 2005, in view of Bird et al. (Science 242:423-242, 1988), in view of Clackson et al. (Nature 352:624-628, August 15, 1991) is maintained.

For the reasons of record listed above in paragraphs 4 and 5 the 102(b) rejection is maintained and accordingly the instant 103(a) rejection is maintained.

9. The rejection of claims 30-37, 43, 47, 54, 55, 57 and 59-61 under 35 U.S.C. 103(a) as being unpatentable over JP(A) H4-169195 (laid open June 17, 1992)/ IDS reference number 24, submitted February 8, 2005, in view of Clackson et al. (Nature 352:624-628, August 15, 1991) is maintained.

For the reasons of record listed above in paragraphs 4 and 5 the 102(b) rejection is maintained and accordingly the instant 103(a) rejection is maintained.

10. The rejection of claims 30-37, 43, 53, 55, 57, 59 and 60 under 35 U.S.C. 103(a) as being unpatentable by JP(A) H2-76598 (laid open March 15, 1990)/ IDS reference number 23, submitted February 8, 2005 is maintained.

For the reasons of record listed above in paragraphs 4 and 5 the 102(b) rejection is maintained and accordingly the instant 103(a) rejection is maintained.

11. The rejection of claims 30-37, 43, 53, 55, 57, 59 and 60 under 35 U.S.C. 103(a) as being unpatentable by JP(A) H2-76598 (laid open March 15, 1990)/ IDS reference number 23, submitted February 8, 2005 is maintained.

For the reasons of record listed above in paragraphs 4 and 5 the 102(b) rejection is maintained and accordingly the instant 103(a) rejection is maintained.

Allowable Subject Matter

12. Claims 38-42 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. Claims 38-42 and 46 are free of the art.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana Harris
Alana M. Harris, Ph.D.
15 November 2005